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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,708

03/11/2005

Hideki Matsui

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EXAMINER

SAJJADI, FEREDOUN GHOTB

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

01/28/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
PPROCESSING@SUGHRUE.COM  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/527,708	<b>Applicant(s)</b> MATSUI ET AL.	
	<b>Examiner</b> FEREYDOUN G. SAJJADI	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15 and 54-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15 and 54-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission and amendment filed on November 12, 2009, that includes a response to the Office action dated September 4, 2009, has been entered. Claim 15 has been amended, claims 51-53 cancelled and claims 54-56 newly added. Accordingly, claims 15 and 54-56 are pending in the application and under current examination.

#### ***New Claim Rejections - 35 USC § 112- New Matter***

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant's claim amendments have necessitated the following new grounds of rejection.

Claims 15 and 54-56 are newly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art (hereafter the Artisan), that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR §1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claim 15 has been amended to recite: the step of "culturing a neuronal cell comprising the polynucleotide in the presence of the compound and said death inducer", and comparing the degree of changes in nerve fibers with a neuronal cell cultured in the presence of a death inducer.

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Applicants state that support for the new limitation may be found *inter alia* at paragraphs [174] to [242] of the specification. However, the published specification appears devoid of such description regarding the step of culturing a neuronal cell in the presence of both the compound and a cell death inducer. The cited parts of the specification fail to disclose either explicitly or implicitly, the steps of treating a neuronal cell with both a drug candidate compound and a cell death inducer, and comparing the changes to a neuronal cell treated with a cell death inducer alone, as claimed. The paragraphs cited by Applicants provide support only for using antisense compounds against NIPK. The working Examples only disclose the addition of a NIPK lentiviral vector in the presence of a cell death inducer. However, such is not commensurate with the instantly claimed method steps.

Thus, at the time the application was filed, an Artisan of skill would not recognize from the disclosure that Applicant was in possession of culturing a neuronal cell in the presence of both a cell death inducer and antisense drug candidates, and further comparing the changes in nerve fibers to a neuronal cell treated with only the cell death inducer, as claimed.

MPEP 2163.06 notes: "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

This is a new matter rejection.

***Response, Maintained & New Claim Rejection - 35 USC § 112-Scope of Enablement***

Claim 15 stands rejected and claims 54-56 are newly rejected under 35 U.S.C. §112, first paragraph, because the specification is not enabling for the full scope of the invention. The rejection set forth on pp. 7-12 of the Office action dated December 13, 2007, pp. 5-7 of the Office action dated June 11, 2008, and pp. 3-4 of the Office action dated December 16, 2008, and pp. 2-5 of the previous Office action dated September 4, 2009 is maintained for claim 15, and further applied to new claims 54-56 for reasons of record.

The previous Office action indicated that the specification is considered only enabling for a method of screening for a compound or its salt that inhibits the expression of an RNA encoding a protein comprising the amino acid sequence set forth as SEQ ID NO: 1, said method comprising introducing into a nerve cell an antisense molecule or ribozyme to RNA of a gene encoding a protein comprising the amino acid sequence set forth as SEQ ID NO: 1, thereby inhibiting the function of said RNA and inhibiting the neurofibrillary degenerating promoting activity of said protein.

Applicants state that the amendment of claim 15 overcomes the rejection. Applicants' arguments have been fully considered, but are not found persuasive.

In response, it is noted that Applicants' amendment of base claim 15 addresses the issues regarding neural cells and the nature of the candidate compound, only in part. Applicants have amended the claim to recite the step of culturing a neuronal cell comprising the polynucleotide encoding SEQ ID NO: 1, in the presence of the compound.

As a first issue, the compound is not recited as specifically directed to an RNA encoding a protein comprising the amino acid sequence set forth as SEQ ID NO: 1, as indicated in the enabled scope. Thus, the antisense polynucleotide, dsRNA or ribozyme may be targeting any number of RNA molecules in the cell. As a second issue, culturing a neuronal cell in the presence of an antisense polynucleotide, dsRNA or ribozyme does not likely result in the delivery of the nucleic acids to the cells, to inhibit NIPK expression. Applicants' claim amendments are clearly an invitation to a skilled artisan to engage in further experimentation, the results of which are unpredictable, thus constituting an undue burden on the skilled artisan.

Thus, the rejection is maintained for reasons of record and the preceding discussion.

***Withdrawn Claim Rejection - 35 USC § 103***

Claim 15 was rejected under 35 U.S.C. §103(a) as being unpatentable over Meyers et al. (U.S. Patent Application Publication No.: 2002/0034780; filed: Mar. 6, 2001), in view of Holocomb et al. (Dev. Biol. 172:307-323; 1995), in the previous Office action dated September 4, 2009. Applicants have amended the claim to introduce new limitations for expression of antisense compounds together with a cell death inducer, not taught by the cited references. Thus, the rejection is hereby withdrawn.

***Conclusion***

**No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/

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Primary Examiner, Art Unit 1633